DATE: June 14, 2004

Docket #: 2004D – 0193

Document Title: Guidance for Industry. Eligibility Determination for Donors of … (HCT/Ps).

Subject: "Who may perform donor testing?" (IV.A/p25)

I believe the response to this question is too brief, inadequate and misleading. The response implies that any laboratory meeting the qualifications set forth in 1271.80 can perform the required testing. In point of fact this is not true. The testing laboratory must additionally be an establishment as defined in1271.3 because testing is one component of manufacture as defined in 1271.3. Obviously establishments must register with the FDA their involvement with HCT/Ps. Most likely an establishment that intends to outsource testing to an otherwise qualified clinical laboratory will have to convince that laboratory to register with the FDA as an HCT/P establishment. I believe that these points about the requirement of the testing laboratory to be registered must be made in the comments about "Who may perform donor testing?'.

Please note attached letter from Ruth R. Solomon, M.D. of FDA

2004D-0193

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

February 28, 2001

Armand M. Karow, Ph.D.
President
Xytex Corporation
1100 Emmett Street
Augusta, GA 30904

Dear Dr. Karow:

This is in response to your letter of February 21, 2001, in which you ask for clarification about the registration of testing laboratories.

As you correctly point out, the response to comment 23, on page 5456 of the preamble to the final rule entitled: Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing, which published in the Federal Register on January 19, 2001 (66 FR 5447), discusses this issue. This final rule requires that all establishments that manufacture human cells, tissues, and cellular and tissue-based products (HCT/Ps) register with FDA and list the HCT/Ps that they manufacture. Manufacture includes the screening and testing of the cell or tissue donor. Certain exceptions from this requirement are listed in section 1271.15 of the rule.

Those CLIA certified laboratories to which you refer some of your tissue donor testing would also have to register, if they perform tests on tissue donor specimens for relevant communicable diseases as defined in the proposed donor suitability rule (64 FR 52696, Sept. 30, 1999). While we acknowledge that CLIA certification is important, and in fact are requiring CLIA certification, there are differences in focus between inspections under CLIA and inspections carried out by FDA such that CLIA certification alone is not adequate. Having all testing laboratories involved with testing of donors of HCT/Ps register with and be inspected by FDA enables the agency to ensure that all testing laboratories are using FDA licensed test kits and following manufacturer's instructions.

Please note that the registration requirement for a testing laboratory that tests specimens from donors of reproductive cells and tissue (but does not test specimens from donors of HCT/Ps currently regulated under 21 CFR, Part 1270) would not become effective until January 21, 2003.

If we can be of further assistance, please do not hesitate to contact us again.

Sincerely,

Ruth R. Solomon, M.D.

Ruth R. Solomon, M.D.
Director, Human Tissue Staff
Office of Blood Research and Review
FDA/CBER